UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2077-6
Program	Prior Authorization/Medical Necessity-Fentanyl Transmucosal
Medication	Abstral** (fentanyl sublingual tablets), Actiq (brand only)** (fentanyl transmucosal lozenge), Fentora** (fentanyl buccal tablet), Lazanda (fentanyl nasal spray), Subsys** (fentanyl sublingual spray), and fentanyl citrate bulk powder**
P&T Approval Date	2/2016, 9/2016, 9/2017, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

1. Background:

Abstral, Actiq, Fentora, Lazanda, Subsys, and fentanyl citrate lozenges (generic Actiq) are rapid-acting opioid analgesics indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg/hour of transdermal fentanyl, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg of oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids while taking a rapid-acting fentanyl product. Abstral, Actiq, Fentora, Lazanda, Subsys and fentanyl citrate lozenges (generic Actiq) must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates.

Dosage form differences provide alternatives for patients who are unable to swallow, have dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

Compounded fentanyl preparations may provide a unique delivery for certain patient-specific conditions and administration requirements. Compounded fentanyl preparations should be made for a single individual and not produced on a large scale. Compounded fentanyl preparations should not be covered if it is being prescribed as an alternative for a commercially available fentanyl product. Therefore, additional criteria will be provided for fentanyl citrate compounds.

2. Coverage Criteria[a, b]:

A. Abstral, Actiq (brand only), Fentora, or Subsys will be approved based on **ALL** of the following criteria:

1. Submission of medical records demonstrating all of the following:

   a. Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented).

-AND-

b. Patient must have at least a **one** week history of **ONE** of the following medications to demonstrate tolerance to opioids:
   1) Morphine sulfate at a dose~~s~~ of greater than or equal to 60 mg/day
   2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
   3) Oxycodone at a dose of greater than or equal to 30 mg/day
   4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
   5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
   6) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

-AND

c. The patient is currently taking a long-acting opioid around the clock for cancer pain

-AND-

d. The patient has a history of failure, contraindication, or intolerance to fentanyl citrate lozenges (generic Actiq)

-AND-

e. The patient has a history of failure, contraindication, or intolerance to Lazanda

-AND-

f. **One** of the following:

   1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.

-OR-

   2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

Authorization will be approved for 12 months.

B. Lazanda will be approved based on **ALL** of the following criteria:

1. Submission of medical records demonstrating all of the following:

   a. Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented).

   -AND-

   b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:
      1) Morphine sulfate at a dose~~s~~ of greater than or equal to 60 mg/day
      2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
      3) Oxycodone at a dose of greater than or equal to 30 mg/day
      4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
      5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
      6) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

   -AND

   c. The patient is currently taking a long-acting opioid around the clock for cancer pain

   -AND-

   d. **One** of the following:

      1) The patient has a history of failure, contraindication, or intolerance to fentanyl citrate lozenges (generic Actiq).

      -OR-

      2) Medical records demonstrate that the patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

      -AND-

   e. **One** of the following:

      1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.

      -OR-

      2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved

at a time. If previous authorizations cannot be terminated, the PA request will be denied.

Authorization will be approved for 12 months.

C. Fentanyl citrate bulk powder or compounded fentanyl** will be approved based on **ALL** of the following criteria:

1. Submission of medical records demonstrating all of the following:

   a. Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented).

   -AND-

   b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:
      1) Morphine sulfate at a doses of greater than or equal to 60 mg/day
      2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
      3) Oxycodone at a dose of greater than or equal to 30 mg/day
      4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
      5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
      6) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

   -AND

   c. The patient is currently taking a long-acting opioid around the clock for cancer pain

   -AND-

   d. A unique dosage form is required for a product that is not commercially available due to patient's age or weight.

   -AND-

   e. **One** of the following:

      1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.

      -OR-

      2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for

alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

Authorization will be approved for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] Criteria is not applicable to groups sitused in Arkansas when medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six (6) months.)

**Abstral, Actiq (Brand ONLY), fentanyl bulk powder, Subsys and Fentora are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.

3. Additional Clinical Programs:

Supply limits may be in place.
Prior Authorization/Notification may be in place.

4. References:

1. Lazanda package insert. Depomed, Inc. Newark, CA. March 2017.
2. Caraceni A, et al. Guidelines for the management of breakthrough pain in patients with cancer. *J Natl Compr Cancer Netw*. 2013; 11 Suppl 1:S29-36.
3. Abstral package insert. Galena Biopharma. Lake Oswego, OR. November 2014.
4. Actiq package insert. Cephalon: North Wales, PA. December 2016..
5. Fentora package insert. Cephalon: North Wales, PA.. December 2016..
6. Subsys package insert. Insys Therapeutics: Chandler, AZ. December 2016.
7. Swarm R, Paice JA, Anghelescu DL, et al. NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain. Version 1.2018. <www.NCCN.org/professionals/physician_gls/pdf/pain.pdf>. Accessed September 5, 2018.

Program	Prior Authorization/Medical Necessity – Fentanyl Transmucosal
Change Control	
Date	Change
2/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Added requirement that patients cannot be receiving concurrent fentanyl products.
11/2016	Administrative change. Added California coverage information.
9/2017	Added criteria for Abstral, Actiq, Fentora, Subsys and bulk or compounded fentanyl citrate. Updated state mandate language.
10/2018	Updated formatting and references.